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| EXAMINER | |
|---|---|
| LAU, JONATHAN S | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/578,507 | EHAMA ET AL. | |
| | Examiner | Art Unit | |
| | Jonathan S. Lau | 1623 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *15-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 Jan 2009 has been entered.

This Office Action is responsive to Applicant's Amendment and Remarks, filed 30 Jan 2009, in which claims 1-4, 11 and 12 are canceled and new claims 15-20 are added.

This application is the national stage entry of PCT/JP04/17037, filed 10 Nov 2004; and claims benefit of foreign priority document JAPAN 2003-381470, filed 11 Nov 2003; currently an English language translation of this foreign priority document has not been filed.

Claims 15-20 are pending and examined on the merits herein.

### *Rejections Withdrawn*

Applicant's Amendment, filed 30 Jan 2009, with respect to claims 1-4, 11 and 12 rejected under 35 U.S.C. 102(b) as being anticipated by Tajima et al. (US Patent Application Publication US 2002/0192177, published 19 Dec 2002, of record) has been fully considered and is persuasive, as claims 1-4, 11 and 12 are canceled and Tajima et al. does not disclose the method comprising administering the composition for a period of time wherein the period is at least one month.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 30 Jan 2009, with respect to claims 1-4, 11 and 12 rejected on the ground of nonstatutory double patenting over claim 1 of U. S. Patent No. 7,182,939 has been fully considered and is persuasive, as claims 1-4, 11 and 12 are canceled and U. S. Patent No. 7,182,939 does not disclose or teach the method comprising administering the composition for a period of time wherein the period is at least one month.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 30 Jan 2009, with respect to claims 1-4, 11 and 12 provisionally rejected on the ground of nonstatutory double patenting over claim 4 of copending Application No. 11/655,134 has been fully considered and is persuasive, as claims 1-4, 11 and 12 are canceled.

This rejection has been **withdrawn**.

The following are new grounds of rejection.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Amended Claims 15 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 15 recites a method comprising providing "a composition for increasing the expression of keratinocyte growth factor (FGF-7) in hair follicle cells".

The specification discloses chemicals, such as adenosine and NECA recited in claim 16 and at page 4, lines 10-20 of the specification which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 15 and 18 are directed to encompass any composition for increasing the expression of keratinocyte growth factor (FGF-7) in hair follicle cells, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these compositions meet the written description requirement of 35 USC 112, first paragraph, due to lacking chemical structural information for what they are and because chemical compositions are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed

by the claim.

As evidence of the breadth of the genus encompassed by the claim, the prior art discloses compositions for increasing the expression of keratinocyte growth factor (FGF-7) in cells:

- Tichelaar et al. (J. Biol. Chem., 2000, 275(16), p11858-11864, cited in PTO-892) discloses expression of FGF-7 in respiratory epithelial cells induced by doxycyline (page 11858, abstract).
- Foster et al. (Differentiation, 2002, 70, p624-632, cited in PTO-892) discloses expression of FGF-7 in prostatic epithelium by the transfection with the transgene (PKS) (page 624, abstract).
- Smith et al. (Prostate Cancer and Prostatic Diseases, 2002, 5, p105-110, cited in PTO-892), discloses sex hormones 17beta-estradiol and testosterone to modulate expression of FGF-7 in prostatic stromal cells, and that this modulation is cell strain-specific (abstract).

The recitation, "for increasing the expression of keratinocyte growth factor (FGF-7) in hair follicle cells", is seen to be merely functional language.

Functional language at the point of novelty, as herein employed by Applicants, is admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does "little more than outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". The CAFC further clearly states that "[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition,

such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials" at 1405(emphasis added), and that "It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus.." at 1406 (emphases added). Further, Smith et al. discloses modulation of expression of FGF-7 is cell strain-specific, and the specification does not provide sufficient description to describe what structural features are necessary for increasing the expression of keratinocyte growth factor (FGF-7) in hair follicle cells.

Thus, Applicants functional language at the points of novelty fails to meet the requirements set forth under 35 U.S.C. 112, first paragraph. Claims employing functional language at the exact point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limited of monopoly asserted" (*General Electric Company v. Wabash Appliance Corporation et al.* 37 USPQ at 468 (US Supreme Court 1938)).

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully described genus, visualize or recognize the identity of the members of the

genus, by structure, formula, or chemical name, of the claimed subject matter, as discussed above in *University of California v. Eli Lilly and Co*. Hence, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art would be unable to fully predict possible physiological activities of any compounds having claimed functional properties in the pharmaceutical compositions herein.

*Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 935 F.2d 1555, 1563 [19 USPQ2d 1111] (Fed. Cir. 1991), makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*Vas-Cath* at page 1116.)

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed compositions for increasing the expression of keratinocyte growth factor (FGF-7) in hair follicle cells, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only

the bovine sequence. The court of *University of California v. Eli Lilly and Co.*, 119 F.3d 1559 [43 USPQ2d 1398] (Fed. Cir. 1997) held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

The court of *In re Curtis*, 354 F.3d 1347 [69 USPQ2d 1274] (Fed. Cir. 2004) held that "a patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when… the evidence indicates ordinary artisans could not predict the operability … of any other species." The court of *Noelle v. Lederman,* 355 F.3d 1343 [69 USPQ2d 1508] (Fed. Cir. 2004) also pointed out that generic claim to anti-CD40CR Mabs lacked written description support because there was no description of anti-human or other species Mabs, and no description of human CD40CR antigen. The court further pointed out that attempt to "define an unknown by its binding affinity to another unknown" failed. The court of *Carnegie Mellon Univ. v. Hoffman-LaRoche Inc.*, 541 F.3d 1115, 1125 [88 USPQ2d 1233] (Fed. Cir. 2008) held that the written disclosure requirement was not met where the claims at issue covered a broad "genus of recombinant plasmids that contain coding sequences for DNA polymerase ...from any bacterial source, [but] the narrow specifications of the[relevant patents] only disclose[d] the ... gene coding sequence from one bacterial source ...."

Therefore, only the structurally defined chemical compounds, but not the full breadth of the claims, meet the written description requirement of 35 USC 112, first

paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that *Vas-Cath* makes clear that the written description requirement of 35 USC 112 is severable from its enablement provision. (See *Vas-Cath* at page 1115.)

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Amended Claims 15-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Gan et al. (US Patent Application Publication 2004/0171693, filing date 18 Aug 2003 of parent provisional application 60/495,915, cited in PTO-892). As the filing date 18 Aug 2003 of provisional application 60/495,915 is relied upon, references to Gan et al. will be found within provisional application 60/495,915.

Gan et al. discloses a method for increasing hair growth (page 1, paragraph 1) administering a composition that comprises adenosine or AMP (adenosine monophosphate, or adenosine 5'-phosphate) (page 3, paragraph 4), meeting limitations of instant claims 16 and 17. Gan et al. discloses the composition applied to healthy hair and scalp to maintain the normal cycle of hair replacement and discloses it will also

increase the diameter of hair already present (page 6, paragraph 3). Gan et al. discloses the composition applied chronically, over the lifetime of the user, preferably for a period of at least about one month (page 7, paragraph 1), meeting limitations of instant claim 15. Gan et al. discloses the embodiment wherein the composition comprises AMP, creatine, L-carnitine and NADH (page 12, paragraph 3). Gan et al. discloses applying the composition to the hair follicle (page 2, paragraph 2) and that dermal pailla cells are present in the hair follicle (page 2, paragraph 3), necessarily meeting limitations of instant claims 18-20.

Note that "increasing the expression of keratinocyte growth factor (FGF-7) in hair follicle cells" is merely considered to be the mechanism of action of a treatment, a method for increasing hair growth comprising administering a composition that comprises adenosine or AMP. It has been settled that the claiming of an unknown property, such as mechanism of action, which is inherently present in the prior art method will not make the claim patentable as set forth in the 102(e) rejection above.

That applicant may have determined a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated and the effect are the same. Thus, the method steps in Gan et al. are the same as the method claimed herein. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims by the same active steps.

Moreover, the mechanism of action of a treatment does not have a bearing on the patentability of the invention if the method steps, i.e., administering the same compound in the same amount to the same or similar patient population, are already known even though Applicant has proposed or claimed the mechanism (e.g., increasing the expression of keratinocyte growth factor (FGF-7) in hair follicle cells). Applicant's recitation of a new mechanism of action for the prior art method will not, by itself, distinguish the instant claims over the prior art teaching the same or substantially identical method steps. Mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Amended Claims 15-20 are provisionally rejected on the ground of nonstatutory double patenting over claims 4 and 5 of copending Application No. 11/655,134. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Claim 4 of copending Application 11/655,134 recites a method comprising applying to scalp or hair roots a composition containing adenosine. Claim 5 of copending Application 11/655,134 recites a narrower genus of this method. As recited above, it is inherent that dermal pailla cells are present in the hair follicle. Therefore, claims 4 and 5 of copending Application No. 11/655,134 recite the same or substantially identical method steps as the instant claims.

Note that “increasing the expression of keratinocyte growth factor (FGF-7) in hair follicle cells” recited in the instant claims is merely considered to be the mechanism of action of a treatment, a method for increasing hair growth comprising administering a composition that comprises adenosine or AMP. It has been settled that the claiming of an unknown property, such as mechanism of action, which is inherently present in the

prior art method will not make the claim patentable as set forth in the provisional double patenting rejection above.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

## ***Conclusion***

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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